

Complete Summary

GUIDELINE TITLE

Universe of Florida patients with acute ischemic brain attack.

BIBLIOGRAPHIC SOURCE(S)

Agency for Health Care Administration (AHCA). Universe of Florida patients with acute ischemic brain attack. Tallahassee (FL): State of Florida, Agency for Health Care Administration; 1999 Mar 5. 16 p. [134 references]

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

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SCOPE

DISEASE/CONDITION(S)

Acute ischemic stroke

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Cardiology

Emergency Medicine

Family Practice

Hematology

Neurological Surgery

Neurology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Emergency Medical Technicians/Paramedics
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To promote improved care for individuals with ischemic stroke
- To assist hospitals and emergency transport services in developing acute stroke intervention protocols

TARGET POPULATION

Adults with acute ischemic stroke less than 3 hours onset

INTERVENTIONS AND PRACTICES CONSIDERED

Emergency medical services (EMS) pre-hospital actions

1. Gather witness information
2. Assess, elevate head, give oxygen, monitor blood pressure and cardiac rhythm, obtain IV access, fingerstick glucose test, 12-lead ECG
3. Radio information to emergency department
4. Use of aspirin and other antiplatelet agents

Emergency department actions

1. Med and neuro exam (National Institutes of Health [NIH] Stroke Scale)
2. Emergency care
3. Diagnostic tests (CBC with platelet count, PT, aPTT, blood glucose, comprehensive metabolic panel, pregnancy test; noncontrast head computed tomography [CT] scan; 12-lead EKG; Chemistry and lipid profiles, CPK/MB or other markers of myocardial infarct; Chest x-ray)
4. Blood pressure control
5. Use of aspirin and other antiplatelet agents
6. Determine eligibility to receive recombinant tissue plasminogen activator (rt-PA)

Thrombolytic treatment of acute ischemic stroke

1. Recombinant tissue plasminogen activator (rt-PA) within 3 hours of stroke onset:
2. Monitor and manage arterial hypertension following rt-PA initiation
3. Monitor for symptoms suggestive of intracranial hemorrhage following rt-PA
4. Manage intracranial hemorrhage following rt-PA (Discontinue rt-PA; emergent noncontrast head CT scan; STAT hematocrit, hemoglobin, PT/INR, PTT, platelet count, fibrinogen, type and crossmatch 3-4 units; alert/consult

hematologist and/or neurologist; prepare to administer cryoprecipitate and platelets; plan for medical treatment/consider surgical intervention)

MAJOR OUTCOMES CONSIDERED

- Length of hospital stay
- Discharge to home rather than to inpatient rehabilitation or nursing home
- Morbidity and mortality associated with acute ischemic stroke

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Internet, National Library of Medicine, National Institutes of Health, and various other sources were used to collect evidence.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not stated

COST ANALYSIS

The State of Florida determined that for every 1,000 patients appropriately treated with recombinant tissue plasminogen activator (rt-PA), costs would increase to approximately \$1.7 million for hospital acute care, including the cost of the drug. The State of Florida also determined that there would be corresponding decreases of \$1.3 million in rehabilitation services and \$4.8 million in nursing home care. This signified improved utilization of health care resources.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

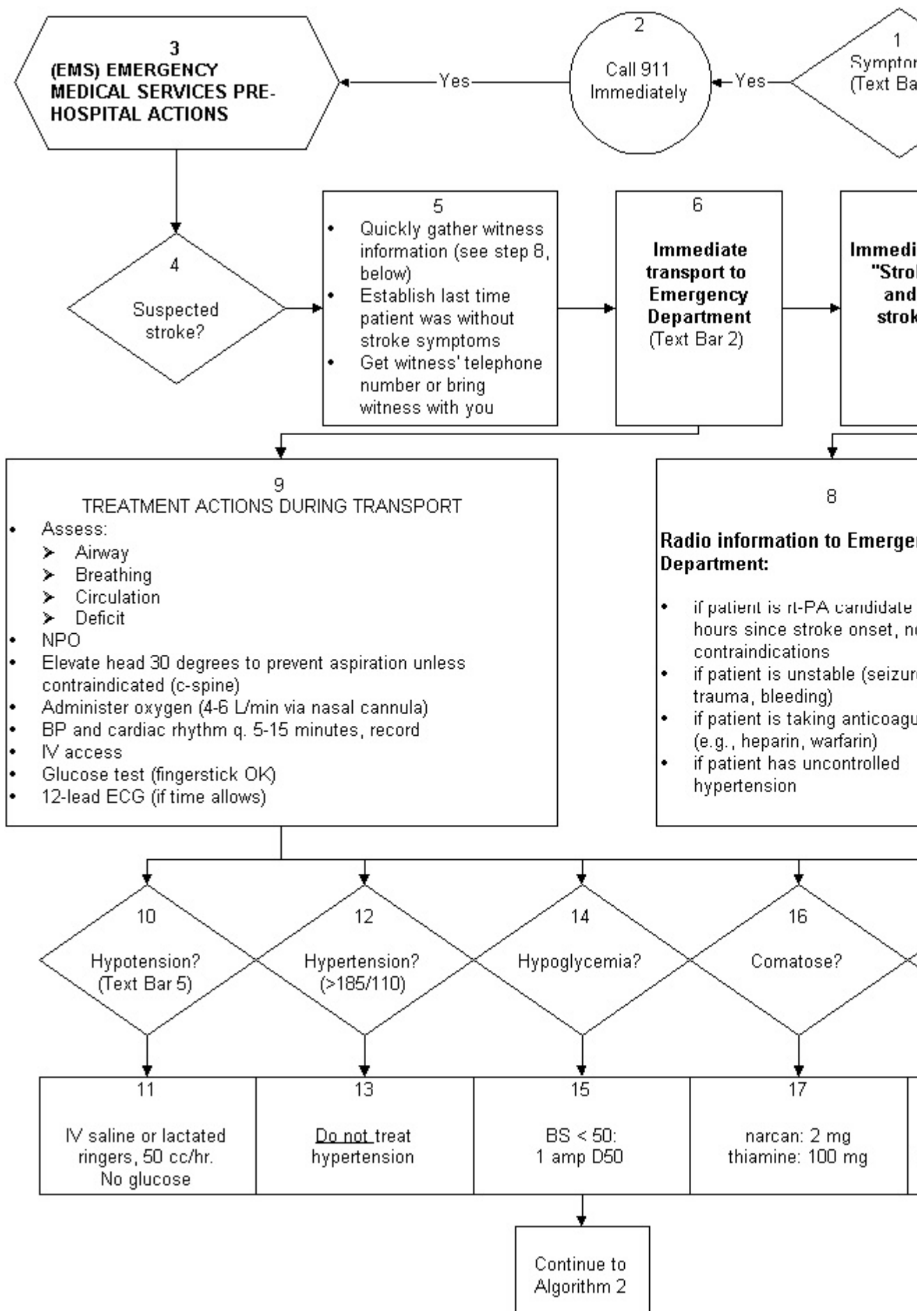
Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

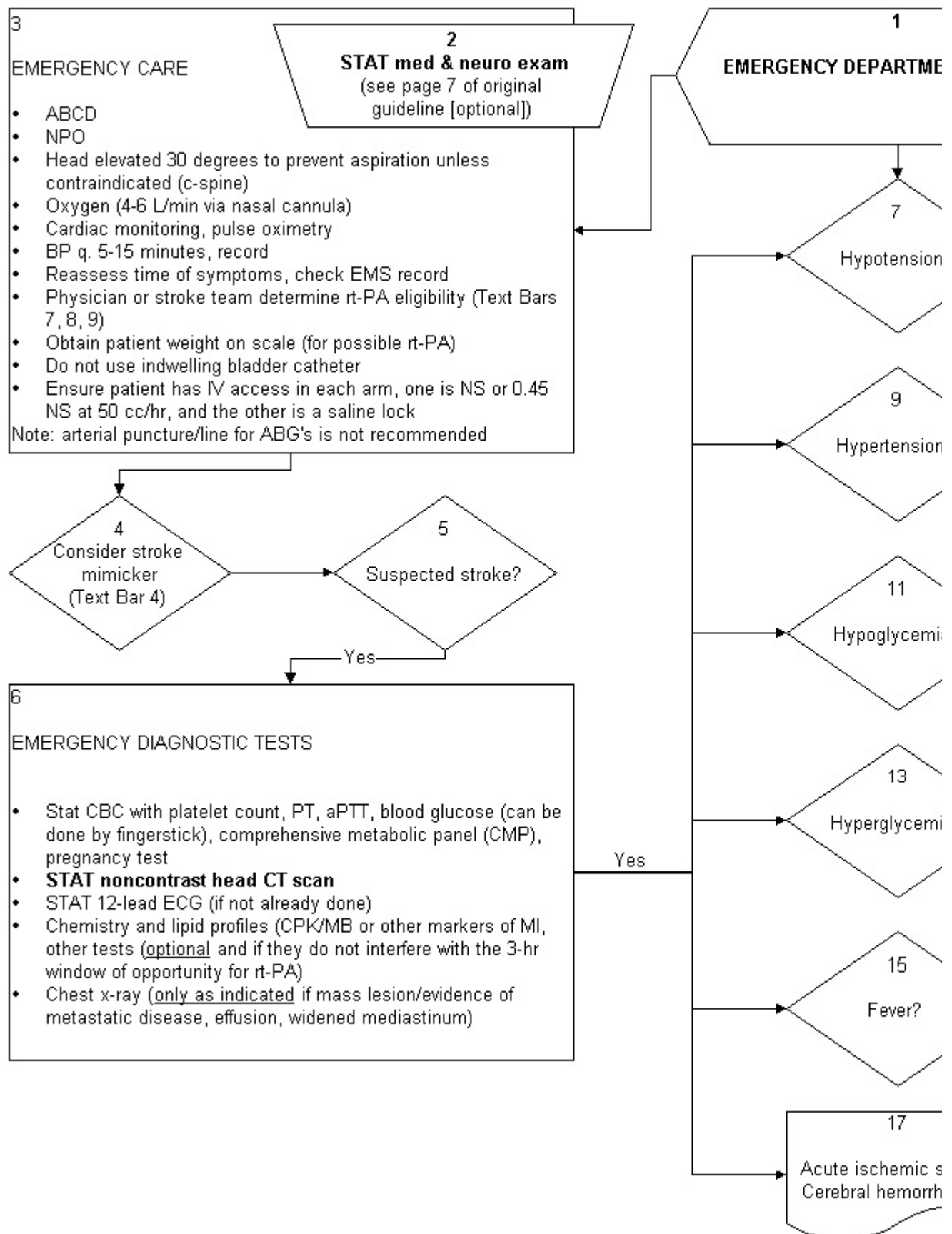
Algorithm 1

Please also refer to the Text Bars that follow these algorithms.



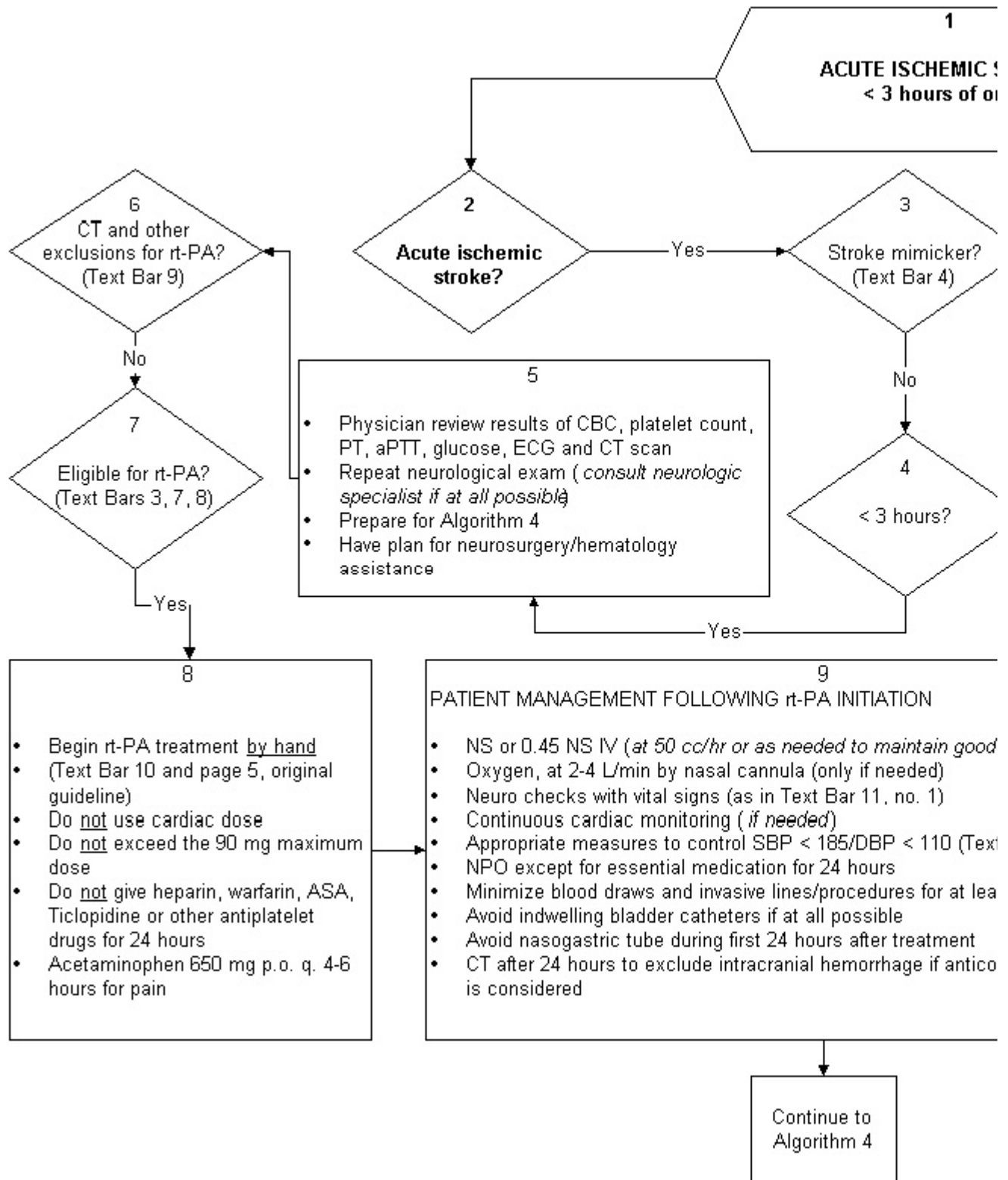
Algorithm 2

Please also refer to the Text Bars that follow these algorithms.



Algorithm 3

Please also refer to the Text Bars that follow these algorithms.



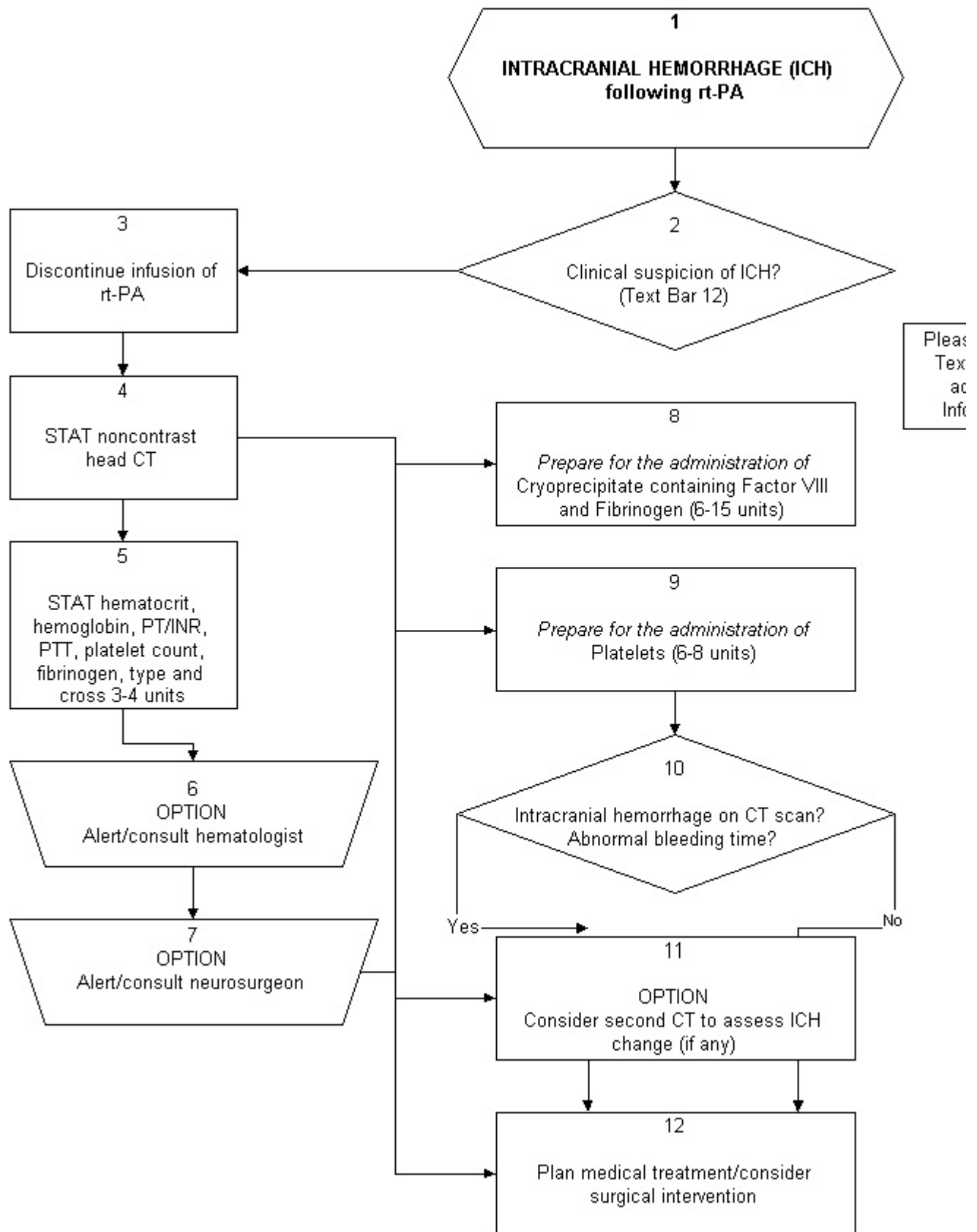
Nota Bene:

On July 20, 1998, Genentech terminated the ATLANTIS stroke trial revealing an extremely small net clinical benefit in patients treated with Activase within 3 to 5 hours of stroke onset.

The ECASS-II trial, overall, showed no difference in clinical benefit in patients treated with Alteplase compared to those who received placebo within 6 hours of stroke onset.

Algorithm 4

Please also refer to the Text Bars that follow these algorithms.



Nota Bene:

Preparation for giving cryoprecipitate and platelets can be initiated at the first suspicion of hemorrhage so that they would be ready if needed.

If coagulopathy persists and during neurosurgical intervention, 2-4 units of fresh frozen plasma may be infused to replenish Factors V and VIII.

The potentiation of bleeding by other adjunctive therapies such as heparin can be reversed by the administration of protamine.

In the NINDS trial, 13 of 22 patients developed symptomatic ICH during the first 36 hours following rt-PA infusion. Only one patient required surgical evacuation of an ICH (TPA Stroke Study Group, 1997).

TEXT BAR 1

Signs of Stroke:

1. Sudden numbness, weakness or paralysis of face, arm or leg - especially on one side of the body.
2. Sudden blurred or decreased vision or loss of total vision in one or both eyes; loss of vision in one half of visual field or double vision.
3. Sudden difficulty speaking or understanding speech
4. Sudden decline in consciousness or mental confusion
5. Sudden severe headache, neck stiffness
6. Sudden loss of balance or coordination

TEXT BAR 2

FACILITIES: Admissions should be limited to emergency medical services (EMS) identified emergency stroke care facilities that offer up-to-date stroke intervention options, permit close observation, frequent medical/neurological assessments and cardiovascular monitoring. Thrombolytic therapy should not be given unless ancillary care staff and facilities to handle bleeding complications are available. Neurosurgical and hematology consultation should be readily available including the ability to transfer the patient quickly to a facility that offers neurosurgical care (within 2 hours of identifying post-rt-PA hemorrhage on head computed tomography [CT] scan).

PHYSICIANS: The diagnosis and treatment of stroke, including the use of thrombolytic therapy, must be performed by a physician with expertise in stroke intervention. CT of the head must be assessed by a physician with expertise in interpreting this imaging study.

EQUIPMENT/STAFF: Emergent CT scanning with competent and prompt interpretation 24 hours a day, 7 days a week requires a CT

technician present in the facility (see page 6 of the original guideline).

TEXT BAR 3

INFORMED CONSENT FOR THE USE OF rt-PA:

Written informed consent for rt-PA is not necessary. However the decision to receive rt-PA should be considered by the patient and significant other(s), in consultation with the physician, and the benefits and risks carefully compared.

In clinical trials conducted by the National Institute of Neurological Disorders and Stroke (NINDS) (National Institutes of Health), and the TPA Stroke Study Group, symptomatic intracerebral hemorrhage within 36 hours after the onset of stroke occurs in 6.4 percent of patients given rt-PA compared to 0.6 percent if rt-PA is not given. Mortality at three months is 17 percent in the rt-PA group and 21 percent in the placebo group. Despite an increase incidence of intracranial hemorrhage, treatment with intravenous (IV) rt-PA within three hours of the onset of stroke improves clinical outcome at three months (N Engl J Med 1995 Dec 14; 333: 1581-7).

Note: An example of written informed consent is provided in the original guideline for physicians requiring written informed consent prior to administering rt-PA.

TEXT BAR 4

MIMICKERS OF THROMBOEMBOLIC STROKE

This list is only provided for information and does not constitute a requirement to eliminate these possibilities through testing or other intervention since this may interfere with the 3-hour window of opportunity for rt-PA treatment initiation.

1. Stroke due to vascular dissection (not an exclusion for rt-PA)
2. Stroke due to vasculitis
3. Meningitis
4. Infectious endocarditis
5. Focal neurologic manifestations of psychiatric origin
6. Multiple sclerosis
7. Migraine
8. Venous thrombosis
9. Herpes simplex encephalitis
10. Status epilepticus
11. Neoplasm
12. Trauma
13. Transient neurological symptoms due to hypo/hyperglycemia
14. Drug abuse (cocaine, phenylpropanolamine, other)

TEXT BAR 5

PRE rt-PA LOW BLOOD PRESSURE CONTROL

Intravenous (IV) infusion of 250 cc bolus of NS if SBP is less than 90. Continuous infusion of NS (no bolus) if SBP is less than 130 in premorbid uncontrolled hypertensives. Then reassess.

TEXT BAR 6

PRE rt-PA HIGH BLOOD PRESSURE CONTROL

1. Do not treat blood pressure if SBP is less than 185/DBP is less than 110.
2. For the purposes of administering IV rt-PA, a stroke patient is considered hypertensive with readings of SBP greater than 185/DBP is greater than 110 on repeated measurements.
3. If SBP is greater than 185/DBP is greater than 110 on repeated measurements, treat with one or two 10 to 20 mg doses of *Labetalol IV push within one hour, and/or *nitroglycerin paste. If these measures do not reduce BP below 185/110 on repeated measurements and keep it down, the patient should not be treated with rt-PA.

*Note: Labetalol is preferred treatment. Both Labetalol and nitroglycerin paste are recommended in the TPA Stroke Study Group Protocol Guidelines, 1997. Some physicians prefer sublingual nitroglycerin for acute BP control and I/V NS is used when the BP is lowered too quickly. Sublingual nitroglycerin cannot be reversed like paste, which can be wiped off.

TEXT BAR 7

rt-PA INCLUSION CRITERIA

1. Greater than or equal to 18 years of age.
2. Clinical diagnosis of ischemic stroke causing a measurable neurological deficit.
3. Clearly defined time of stroke onset (less than 180 minutes before the initiation of IV rt-PA).

Note: if significant abnormal lucency on CT scan, the stroke may have occurred earlier. Retake history.

TEXT BAR 8

rt-PA PRECAUTIONARY AND WARNING CRITERIA

These conditions present potential increased risks for rt-PA treatment and should be weighed against anticipated benefits.

1. Major surgery, serious trauma excluding head trauma less than 2 weeks.
2. Gross gastrointestinal (GI) or urinary tract hemorrhage less than 3 weeks.
3. Arterial puncture at a noncompressible site less than 1 week.
4. Lumbar puncture less than 1 week.
5. Blood glucose less than 50 mg/dL or greater than 400 mg/dL.
6. Myocardial infarction (MI) or pericarditis less than 6 weeks.
7. Subacute bacterial endocarditis.
8. Severe hepatic or renal disease (hemostatic defects)
9. Sustained hypotension (Text Bar 5 - can be a sign of extracranial hemorrhage).
10. Severe neurological deficit (for example, a score greater than 22 on NIH Stroke Scale at presentation - see Text Bar 7, or CT evidence of a large MCA territory infarction, i.e., substantial edema, mass effect or midline shift - sulcal effacement or blurring of gray-white junction greater than 1/3 of MCA territory).
11. Coma (consideration should be given to the possibility of a stroke secondary to basilar artery occlusion which is generally fatal or debilitating if left untreated).
12. Pregnancy and lactation (rt-PA should be given if clearly needed).

Note: the safety and efficacy of rt-PA treatment in patients with rapidly improving symptoms or isolated mild neurological deficits, i.e., ataxia alone, dysarthria alone, sensory loss alone or minimal weakness alone has not been evaluated.

TEXT BAR 9

rt-PA EXCLUSION CRITERIA

These conditions present increased risk of bleeding:

1. Evidence of intracranial hemorrhage on CT (see original guideline, page 6 for other imaging).
2. Symptoms of subarachnoid hemorrhage even with normal CT (severe head or neck pain, somnolence, stupor).
3. Active gross internal bleeding
4. Prior intracranial hemorrhage
5. Known bleeding diathesis not limited to:
 - a. Platelet count less than 100,000/mL³
 - b. Heparin less than 48 hours and still elevated aPTT (greater than upper limit of normal).
 - c. On oral anticoagulants (e.g., warfarin sodium) or PT greater than 15 seconds (INR greater than 1.7)
6. Intracranial surgery, serious head trauma, or previous stroke less than or equal to 3 months
7. On repeated measurements, SBP greater than 185/DBP greater than 110 at the time of treatment initiation and unsuccessful

treatment to reduce SBP less than 185/ DBP less than 110
(Text Bar 6)

8. Known arteriovenous malformation, aneurysm or neoplasm
9. Stroke onset greater than 3 to 6 hours (See Nota Bene)
10. Seizure at stroke onset

TEXT BAR 10

rt-PA DOSAGE

0.9 mg/kg (90 mg maximum dose). 10% given in bolus by hand (to prevent accidental total dose) over one minute, followed by continuous IV infusion over 60 minutes (see original guideline, page 5, for dosage information).

TEXT BAR 11

MONITORING AND MANAGEMENT OF ARTERIAL HYPERTENSION FOLLOWING rt-PA INITIATION

Note: the administration of rt-PA should be discontinued if two successive blood pressure readings over 10 minutes are SBP less than 185/DBP less than 110 mmHg.

1. *Monitor BP during the first 26 hours following rt-PA injection:
 - q. 15 minutes for 2 hours
 - q. 30 minutes for 6 hours
 - q. 1 hour for 18 hours
2. If DBP is greater than 140 mmHg on repeated measurements:
 - IV Sodium Nitroprusside (0.5-10 micrograms/kg per minute)
 - Monitor BP q. 15 minutes during infusion of Sodium Nitroprusside
 - Observe for hypotension
3. If SBP is greater than 230 mmHg or if DBP ranges from 121-140 mmHg on repeated measurements:
 - IV Labetalol 20 mg over 1 to 2 minutes. Repeat or double q. 10 minutes up to 150 mg. Alternatively, following the first bolus or Labetalol, infuse 2 to 8 mg per minute of Labetalol and reinfuse until desired BP
 - Monitor BP q. 15 minutes during Labetalol administration
 - Observe for hypotension
 - If no satisfactory response infuse Sodium Nitroprusside (0.5 to 10 micrograms/kg per minute).
 - Continue monitoring BP
4. If SBP is 180-230 mmHg or if DBP is 105-120 mmHg for 2 readings 5-10 minutes apart:
 - IV Labetalol 10 mg over 1 to 2 minutes. Repeat or double q. 10 to 20 minutes up to 150 mg. Alternatively,

following the first bolus of Labetalol, infuse 2 to 8 mg per minute of Labetalol and reinfuse until desired BP

- Monitor BP q. 15 minutes during Labetalol administration
- Observe for hypotension

*Use arm without the rt-PA infusion

TEXT BAR 12

SYMPTOMS SUGGESTIVE OF INTRACRANIAL HEMORRHAGE FOLLOWING rt-PA

1. Increased neurologic deficit, including deteriorating level of consciousness.
2. New headache or increasing headache
3. Acute hypertension (two successive readings over 10 minutes that are SBP greater than 185/DPB greater than 100 mmHg following the infusion of rt-PA)
4. Nausea and vomiting
5. Lethargy

CLINICAL ALGORITHM(S)

Algorithms are provided for:

1. Emergency medical services (EMS) pre-hospital actions;
2. Emergency department actions;
3. Acute ischemic stroke less than 3 hours; and
4. Intracranial hemorrhage following rt-PA administration

See "Major Recommendations."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

1. Improved care for individuals with ischemic stroke and the appropriate use of rt-PA may limit permanent damage and prevent complications, disabilities, and death.
2. Appropriate use of rt-PA within three hours of stroke onset improves clinical outcome at three months (mortality at three months was 17 percent in the rt-PA group and 21 percent in the placebo group), despite an increased incidence of intracranial hemorrhage.

3. In clinical trials conducted by the National Institute of Neurological Disorders and Stroke (NINDS) and the TPA Stroke Study Group, it was determined that the average length of hospital stay was significantly shorter in patients treated with recombinant tissue plasminogen activator (rt-PA) and that discharge was more likely to be to the patient's home than to inpatient rehabilitation or a nursing home.

POTENTIAL HARMS

Possible complications associated with the use of recombinant tissue plasminogen activator (rt-PA) are arterial hypertension and intracranial hemorrhage. In the NINDS and TPA Stroke Study Group trials, 6.4 percent of patients developed symptomatic intracranial hemorrhage (ICH) during the first 36 hours following rt-PA infusion compared to 0.6 percent if rt-PA is not given.

Subgroups Most Likely to Be Harmed:

The following conditions present increased risk of bleeding and treatment with rt-PA is excluded:

- Evidence of intracranial hemorrhage on computed tomography (CT) scan
- Symptoms of subarachnoid hemorrhage even with normal CT scan
- Active gross internal bleeding
- Prior intracranial hemorrhage
- Known bleeding diathesis not limited to:
 - Platelet count less than 100,000/cubic millimeter
 - Heparin less than 48 hours and still elevated aPTT (greater than the upper limit of normal)
 - On oral anticoagulants (e.g., warfarin sodium) or PT > 15 seconds (INR >1.7)
- Intracranial surgery, serious head trauma, or previous stroke in less than or equal to 3 months ago
- On repeated measurements, systolic blood pressure (SBP) greater than 185, diastolic blood pressure (DBP) greater than 110 at the time of treatment initiation and unsuccessful treatment to reduce SBP less than 185, DBP less than 110
- Known arteriovenous malformation, aneurysm or neoplasm
- Stroke onset greater than 3-6 hours
- Seizure at stroke onset

The following conditions present potential increased risks for rt-PA treatment and should be weighed against anticipated benefits:

- Major surgery, serious trauma excluding head trauma less than two weeks
- Gross gastrointestinal or urinary tract hemorrhage less than weeks
- Arterial puncture at a noncompressible site less than one week
- Lumbar puncture less than one week
- Blood glucose less than 50 mg/dL or greater than 400 mg/dL
- Myocardial infarction or pericarditis less than six weeks
- Subacute bacterial endocarditis
- Severe hepatic or renal disease (hemostatic defects)
- Sustained hypotension

- Severe neurological deficit (for example, a score greater than 22 on NIH Stroke Scale at presentation, or CT evidence of large MCA territory infarction, i.e., substantial edema, mass effect, or midline shift - sulcal effacement or blurring of gray-white junction greater than 1/3 of MCA territory)
- Coma (consideration should be given to the possibility of a stroke secondary to basilar artery occlusion which is generally fatal or debilitating if left untreated)
- Pregnancy and lactation (rt-PA should be given if clearly indicated)

NOTE: The safety and efficacy of rt-PA treatment in patients with rapidly improving or isolated mild neurological deficits (i.e., ataxia alone, dysarthria alone, sensory loss alone, or minimal weakness alone) has not been evaluated.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

1. These guidelines are not intended to be used as fixed protocols. They are strategies for patient management which are not entirely inclusive or exclusive of all methods of reasonable care that might obtain comparable results. They do permit the consideration of the unique exigencies of each individual and for available resources. Many patients will require more treatment or less treatment. All patients require individual consideration.
2. Treatment must be based on patient need(s) as well as professional judgment. Therefore, these guidelines should be tailored to fit distinctive patient needs that are affected by the medical setting, by available resources and by other factors. Certain deviations may be justified by individual circumstances.
3. While standards are intended to be rigid and mandatory, making exceptions rare and troublesome to justify, guidelines are more flexible, but it is advisable that they be followed as closely as is prudent.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The Florida Agency for Health Care Administration (AHCA), Department of Health (DOH), and the Florida Medical Association (FMA) disseminated the guideline to Medical Directors of Hospitals, Emergency Departments, Stroke Units and Emergency Medical Services throughout the State of Florida.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Agency for Health Care Administration (AHCA). Universe of Florida patients with acute ischemic brain attack. Tallahassee (FL): State of Florida, Agency for Health Care Administration; 1999 Mar 5. 16 p. [134 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Mar 5

GUIDELINE DEVELOPER(S)

Florida Agency for Health Care Administration - State/Local Government Agency [U.S.]

SOURCE(S) OF FUNDING

Florida Agency for Health Care Administration

GUIDELINE COMMITTEE

Florida Stroke Medical/Surgical Guideline Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

Florida Department of Health - State/Local Government Agency [U.S.]
Florida Medical Association - Medical Specialty Society

GUIDELINE STATUS

This is the revised release of the guideline.

Guidelines are revisited every three years or less. Review is based on valid scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Agency for Health Care Administration (AHCA), Medical Guidelines Clearinghouse Program, 2727 E. Mahan Drive, Tallahassee, FL 32308-5403.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 19, 1999. The information was verified by the Florida Agency for Health Care Administration on December 20, 1999.

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